In the war against microbes, one of the mightiest weapons is the steam sterilizer. Steam, considered the ideal sterilant, is recommended for sterilizing devices that are heat and moisture stable. Steam is nontoxic, readily available, and low in cost relative to other technologies. With the exception of prions, the particles responsible for Creutzfeldt-Jakob disease, steam sterilization readily kills microorganisms, including bacteria (including those in a spore state), viruses, and fungi responsible for life-threatening infections. Assuming all of the processes leading up to the sterilization process, such as cleaning, drying, packaging, and cycle selection, are carried out correctly; the steam quality is appropriate; and the sterilizer is working properly, there is every reason to have high confidence in the sterilization process.

This is a refresher on basics of steam sterilization.

The sterilization standard

The standard for sterilization is expressed mathematically as $10^{-6}$ and as a sterility assurance level (SAL). Stated simply, this means that at the end of the sterilization cycle, there is $\leq 1$ chance in 1 million that there are any remaining viable microorganisms.

To test whether a sterilizer is capable of achieving this standard, a biological indicator is placed in the sterilizer, and the cycle is run. The biological indicator for a steam sterilizer contains roughly 1 million spores of *Geobacillus stearothermophilus* bacteria. These bacteria are the most resistant to steam sterilization, and bacterial spores are more difficult to kill than vegetative bacteria.

Cleaning makes a difference

In real life, devices placed in a sterilizer contain far less than a million microorganisms, and the bacteria are most likely be in a vegetative state, not the more resistant spore state. Several studies have demonstrated that the amount of bioburden on instruments after cleaning is actually quite low. Chan-Myers et al found the bioburden associated with rigid lumened devices before cleaning was low—approximately 132 CFU (colony forming units) per device—and after cleaning, 83% of devices had less than $10^{-2}$ (100) CFU. Rutala found that after 50 general surgery instruments were cleaned, 72% had 0 to 10 CFU, 14% had 11 to 100 CFU, and 14% had more than 100 CFU. The bioburden on flexible endoscopes such as colonoscopes is higher because the bacterial count in the colon is naturally high. But after cleaning, even these devices have been shown to contain well below a million microorganisms.

A margin of safety

In short, the sterilizer must demonstrate the ability to kill far more microorganisms than normally would be found on a surgical device, especially after cleaning. There is no commonly accepted standard in the US for “clean.” Whether an item is clean is typically determined through visual inspection.

Before the Food and Drug Administration (FDA) clears a sterilizer for market, the sterilizer manufacturer must demonstrate that the sterilizer can achieve an SAL of $10^{-6}$ in half the cycle time for which it is programmed. For example, if the sterilizer is programmed for a cycle time of 4 minutes at 270° F (132° C), the actual kill must occur in 2 minutes. The extra 2 minutes is considered “overkill” and provides an additional—and tremendous—margin of safety. The sterilizer is designed so the operator cannot adjust the cycle to less than the time required for overkill in this cycle.
Understanding the sterilization cycle

At the end of the sterilization cycle, the operator should check the sterilizer print-out to determine if the proper time and temperature were achieved and whether the exposure time was sufficient. Knowing what those values should be is critical, but it is also important to understand their significance.

Steam quality

Proper steam quality is a key factor in preventing wet packs. When water is heated at atmospheric pressure, a temperature of 212° F (100° C) is achieved, and water will boil. When the water and the water vapor are the same temperature, the steam is termed saturated steam. The saturated steam temperature of 212° F (100° C) at atmospheric pressure is not high enough to kill heat-resistant microorganisms. A pressure vessel or sealed container—ie, the sterilizer chamber—is required to increase the saturated steam temperature to 250° F (121° C), the lowest temperature required for sterilization. Steam is said to be 100% saturated when there is no liquid present. Steam quality is generally recommended to be at least 97%, meaning there is less than 3% liquid present. Steam quality can be determined by the sterilizer company service personnel or an in-hospital engineer.

Three critical factors

The 3 critical factors in steam sterilization are time, temperature, and moisture.

Time

Microorganisms exposed to saturated steam at a constant temperature do not all die at the same time. Their death is typically expressed in a straight-line survivor curve. In the example below, the initial number of microorganisms to be killed is 1 million (the same number that might be contained in the biological indicator). One million microorganisms is expressed as $10^6$ (not to be confused with $10^{-6}$).

As exposure to the sterilant occurs, the microorganisms begin to die. When 90% of the microorganisms die, 100,000 will have survived. This is considered a 1 log reduction. When 90% of the remaining 100,000 microorganisms die, 10,000 will have survived. This is considered a 2 log reduction. Progressive 90% or 1 log reductions will result in 1,000 survivors, followed by 100 survivors, followed by 10 survivors, followed by 1 survivor. At this point, a 6 log reduction will have been achieved.

In a 4-minute cycle at 270° F (132° C), a 6 log reduction will have been achieved at 2 minutes. For all practical purposes, all of the microorganisms should have been killed at this point. As the cycle progresses, 90% or 1 log reductions continue until 0.000001 of microorganisms will have survived, or a 12 log reduction (an SAL of $10^{-6}$), will have been achieved.

Another term used when discussing the survivor curve is the D value. The D value is the amount of time it takes for a 1 log reduction to occur. D values vary according to the microorganism in question. The more resistant the organism, the greater the D value.

Why extended cycles?

You might ask why so many newer devices require an extended cycle, an exposure time longer than the more common 4 minutes. Reasons include complexity of the device, lumen size, or dense configuration of a set. Some materials used in containment devices, such as certain plastics or a combination of plastic and metal, may also require a longer exposure time. When device manufacturers validate sterilization instructions for their devices they inoculate the devices with $10^6$ Geobacillus stearothermophilus bacterial spores, placing theses spore populations in the least accessible areas of the devices, and determine how long it takes for the spores to be inactivated, or half the exposure time required to achieve an overkill. The overkill time is the exposure time provided in the instructions.

When a device exposed to prions is sterilized, the cycle time is also extended. The recommended time is 18 minutes at 270° F (132° C). In this instance, the extended cycle time relates to the resistance of the organism.
Temperature

The lower the temperature, the longer the time required for sterilization to occur. For example, if it takes 12 minutes to kill 1 million spores of *Geobacillus stearothermophilus* at a temperature of 250° F (121° C), raising the temperature to 270° F (132° C) decreases the time required to less than 1 minute.

It is important to note that if the steam is not saturated, the microorganisms may not be killed even though the time and temperature are appropriate. Increasing the exposure time in the event of a failed biological indicator is not the proper corrective action because it does not ensure the presence of saturated steam—one of the requisites for steam sterilization.

Moisture

One reason dry heat is rarely used for sterilization in health care facilities is the time required for sterilization. What requires 6 hours to sterilize at 250° F (121° C) in dry heat may require only 15 minutes at 250° F (121° C) in moist heat. Moisture reduces the time necessary to denature or coagulate proteins, which causes microorganisms to be killed in steam.

One impediment to adequate moisture is trapped air. Air and steam do not mix well, and air can prevent steam contact with a device. In health care facility sterilizers, air is removed from the chamber either by the force of gravity (a gravity displacement sterilizer or a gravity cycle), a vacuum (prevacuum sterilizer or cycle), or pulse pressure (a series of steam pressure pulses).

Positioning of devices in a gravity displacement sterilizer or cycle is critical. Medicine cups and other concave devices should be inverted to prevent air entrapment. In a vacuum cycle, concave items are inverted to prevent pooling of condensate.

Testing for residual air

Residual air in the chamber can be the result of an air leak caused by a faulty gasket or other defect. A Class 2 indicator, commonly referred to as a Bowie-Dick test, is used to assess the efficiency of air removal in a cycle where air is removed by vacuum. A Bowie-Dick test may be user assembled, but most facilities employ a commercially prepared test. The Association for the Advancement of Medication Instrumentation recommends performing this test each day the sterilizer will be used before the sterilizer is used to sterilize devices.

To standardize test procedures and reduce the potential for error, the test should be performed at the same time each day. In the operating room, it may be most convenient to have the night staff perform the test just prior to the end of the night shift and the start of the day shift. The Bowie-Dick test is run in an empty chamber. To properly heat the sterilizer, a cycle should be run omitting the dry time prior to performing the Bowie-Dick test.

Ensuring a safe process

Understanding the basic function of a steam sterilizer and correctly interpreting the printout are part of quality monitoring and facilitate processes that have a major impact on patient safety. Processing of surgical instruments is a complex process. Though starting a cycle may require only the push of a button, sterilization is not magic. An excellent process and outcome require in-depth knowledge and critical thinking skills. Sound knowledge of the principles of steam sterilization will help ensure a consistent and safe process. ☞

—*Cynthia Spyr, RN, MA, MSN, CNOR*
Independent Clinical Consultant

References

